

Serial No. 10/726,962

PATENT

REMARKS

In the Office Action dated September 3, 2008 claims 28 to 34 were pending of which claims 28 to 34 were rejected.

In particular:

- Claims 28 to 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Andreas et al (US 7,147,656) in view of Hartley et al (US 6,939,370).

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CLAIM AMENDMENTS

No claim amendments are made in this response.

DISCUSSION

The Examiner has maintained the previously recited rejections on two particular grounds. First, she believes that the references show releasable mounting in three places where the term releasable mounting is given its broadest interpretation. Second, she believes that the outermost tube is movable with respect to the other tubes and that this fact meets the limitations of the claims.

Claim 28

As we have explained previously Claim 28 defines an assembly of a deployment device and a prosthesis with a specific set of features. These features include a specific arrangement where the prosthesis is releasably fastened to the deployment device in three places as follows;

- the central portion of the prosthesis is releasably fastened to the manipulator
- the proximal end of the prosthesis is fastened to the distal end of the deployment catheter, and
- the distal end of the prosthesis is fastened to the nose cone dilator.

This particular arrangement enables the prosthesis to be manipulated during deployment and selectively released from its fastenings.

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The reference Andreas et al (US 7,147,656) does not teach a releasable retention at three points but only at one point. The Examiner has suggested that the fact that the prosthesis is held in a delivery device means that the prosthesis is releasably fastened. She states in support of her stance that a particular method of fastening is not stated and therefore she is entitled to give a broadest reasonable interpretation to the word fastened.

We submit that a reasonable interpretation of "fastened" and in distinction "held", as is used in Andreas et al, indicates that these terms mean different things and are not interchangeable. One can hold a cup in ones hand but if the cup is fastened to ones hand then, even if one is no longer holding it, it will not drop. That is, fastened requires some further thing actually connecting one thing to another. In the context of this claim, we submit that the word fastened does not need any definition of the means of fastening. Its meaning is clear.

With respect, we submit that the interpretation which has been given by the Examiner is anything but reasonable and has missed the full import of the phrase "releasable fastening". Surely, in its broadest reasonable interpretation the word "fasten" must mean that there is present some arrangement for connecting one thing with another. Further the word "releasable" must mean that there is some arrangement present by which the fastening can be released.

In the reference Andreas et al there is certainly one releasable fastening which is described at column 2 line 54 and 55 as:

"... with the leading portion everted and fixed to an outer portion of a catheter, This leading is referred to as the "fixed end." ..."

In fact, the reference Andreas et al does not teach a specific method of release of the prosthesis but it does describe without any illustration for support that:

"...Once the prosthesis 30 is fully deployed, the outer tube 32 would be disengaged from the fixed end 42 of the prosthesis, e.g., by rotating or otherwise separating the catheter from the prosthesis, leaving the prosthesis 30 in place, as shown in FIG. 2D."

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Alternatively the specification describes severing the prosthesis at any desired length, again without any illustrative teaching of how such a severing could be done.

There no teaching or suggestion anywhere in Andreas et al that any other portion of the prosthesis is releasably fastened to any portion of the delivery device. There is reference in several places to the prosthesis being held within the delivery catheter but this is not a releasable fastening or a fastening at all when considered in the light of the reasonable interpretation discussed above. If the prosthesis was fastened to any part of the Andreas et al device other than the fixed end then it could not be slid out and everted during the delivery process as described.

At column 2 lines 57 it is stated that"

"The remainder of the prosthesis which remains in its narrow diameter configuration is held within a passage or lumen of a delivery catheter, and means are provided for pushing the "advancable end" of the prosthesis which is in the lumen forwardly relative to the fixed end. In this way, the leading edge of the prosthesis moves forward continuously relative to the fixed end as it everts radially outwardly."

The stent delivery catheter (10) of Andreas et al has an outer catheter (32) to which the prosthesis (30) is connected at what is termed in Andreas et al the "fixed end" of the prosthesis. There is no other connection of the prosthesis with any portion the stent delivery catheter.

For these reasons we submit that there is no teaching or suggestion in Andreas et al of releasably mounting a prosthesis at multiple points to separately movable parts of a delivery device so that these points are separately movable. Separately movable can include rotation, for instance, and as there is no fastening of the prosthesis in Andreas et al other than at the fixed end then portions other than the fixed end could not be rotated.

The second point which the Examiner commented upon in her Response to Arguments is in relation to relative movement on the various components. She

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suggests that since the other tubes move then there is relative movement of the outside tube.

The device depicted in Andreas et al has an outer tube (30), a middle tube (34) and an inner tube (36). It is described as;

"The catheter body 12 comprises an outer tube 32, a middle tube 34 which coaxially and slidably mounted within a lumen of the outer tube 32, and an inner tube 36 which is slidably and coaxially mounted within a lumen of the middle tube 34. Inner tube 36 has a central lumen for receiving a guidewire, as described in detail below."

Hence in Andreas et al it is the outer component which is fixed and the two inner components which move. The prosthesis, as discussed above, is only releasably fastened at one of its ends to the outer tube.

We draw the Examiners attention to the construction of the deployment device as claimed in Claim 28 of the present application and the parts of the prosthesis which are releasably fastened to the respective parts. In this claim there is defined a central catheter, a deployment catheter co-axially around the central catheter and a manipulator coaxially around the deployment catheter. Each of the deployment catheter and the manipulator are defined in Claim 28 as being slidable longitudinally with respect to the portion of the device upon which it is mounted.

Whereas in Claim 28 it is the central portion of the prosthesis which is releasably mounted to the manipulator, the outermost component, as is discussed above in detail, in Andreas et al it is one of the ends which is fixed to the outer tube. Regardless of what is relatively movable with respect to another component there is no teaching or suggestion in Andreas et al that a central portion of the prosthesis is joined to an outer component and that this portion can be moved independently of the other portions.

For these reasons we submit that there is no teaching or suggestion in Andreas et al of mounting a central portion of a prosthesis to an outermost slidable component so as to be separately movable.

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The reference Hartley et al (US 6,939,370) also does not teach or suggest mounting a prosthesis at multiple points including a central portion of the prosthesis so as to be separately movable nor does it teach or suggest that there are three separately movable components with portions of the prosthesis releasably mounted to each them respectively.

We submit that Claim 28 is patentable over Andreas et al (US 7,147,656) in view of Hartley et al (US 6,939,370).

Claims 29 to 34

Claims 29 to 34 depend from Claim 28 and, as discussed above, claim 28 is patentable over Andreas et al (US 7,147,656) in view of Hartley et al (US 6,939,370) whether considered singly or in combination and hence Claims 29 to 34 are also patentable over Andreas et al (US 7,147,656) in view of Hartley et al (US 6,939,370).

The re-examination and consideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this response and amendment.

Respectfully submitted,

David Ernest Hartley
Ian Nixon
Peter John Messer

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By Richard J. Godlewski
Richard J. Godlewski
Reg. No. 30,056
(812) 330-1824